REMARKS

Prior to the present amendment, claims 1-20 were pending in the present application. By the present amendment, claims 1, 4, 7, 9, and 10 have been cancelled and Applicants reserve the right to prosecute the subject matter of these claims in an application that claims priority to the present application. Claims 21-24 have been added. Therefore, claims 2-3, 5-6, 8, and 11-24 are pending in the present application.

Support for claims 21 and 22 can be found, for example, in the specification on page 5, lines 4-6; support for claim 23 can be found, for example, at page 5, lines 21-25; and support for claim 24 can be found, for example, on page 5, lines 17-18. Claim 11 has been amended to recite administering xenon to a "newborn subject in need of analgesia." Claim 12 as been amended to recite administering xenon to a "fetal subject in need of analgesia." Support for these amendment can be found, for example, in the preamble of original claims 11 and 12.

Summary

The present claims are directed to using xenon to provide analgesia to a newborn or fetal subject in need thereof. As described in the "Background" section of the present specification, the human fetus and newborn are known to experience pain sensation. A greater concern is that untreated pain in the newborn may affect central nervous system development resulting in long-term physiological and psychological consequences. (See page 1, lines 8-12).

The present specification also notes that the expectation that an analgesic drug will exert the same effect on adults and neonates has been challenged by a report that nitrous oxide, while known as an anesthetic and analgesic in adults, was ineffective as an analgesic in neonatal rats. (See page 1, line 22 to page 2, line 2). If extrapolatable to humans, this would mean that nitrous oxide is ineffective as an analgesic agent in neonatal and fetal subjects. Up until the present invention, a similar rationale was thought to apply to the use of xenon as an analgesic agent, particularly given the similar properties and mechanism of action of nitrous oxide and xenon. (See page 2, lines 1-2). For example, both xenon and nitrous oxide are inorganic gases and NMDA antagonists (See page 18, line 9 to page 19, line 27).

Priority

The Examiner requests that the specification be amended to include priority information. The specification has been accordingly amended.

Rejection of Claims Under 35 U.S.C. 101 and 112

Claims 1-10 stand rejected for allegedly being drawn to non-statutory matter and allegedly not reciting any active positive steps. Without conceding to the propriety of this rejection, Applicants submit that the cancellation or amendment of claims 1-10 renders this rejection moot.

Rejection of Claims Under 35 U.S.C. 102 by Ohashi

Claims 11 and 13 stand rejected for being allegedly anticipated by Ohashi et al. (Anesthesiology 2002, 96, A1291) ("Ohashi"). Applicants traverse this rejection. The exact publication date of this Ohashi abstract is unclear. It appears that the abstract is a summary of a poster presentation that occurred on October 16, 2002. Specifically, prior to the "Introduction" section, the Ohashi abstract provides a date: "Wednesday, October 16, 2002, 2:00 pm." Further, at the end of the abstract, there is a reference to a "Poster Discussion: Pediatric Anesthesia: Pain (2:00 PM-3:30 PM)." Therefore, it appears that the poster discussion that the abstract references was no earlier than October 16, 2002. No further date is provided. The present application claims priority to a Great Britain patent application with a filing date of August 5, 2002, which is before the October 16, 2002 date referenced in the Ohashi abstract. As such, Applicants submit that Ohashi is not proper prior art and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 102 by Fukara

Claims 11-13 and 17 stand rejected as being allegedly anticipated by Fukara et al. (Prog. Neuro-Psychopharmacol. & Biol Psychiat., 2004, 24, 1357-1368) ("Fukara"). Applicants traverse this rejection. According to the Examiner, Fukara discloses treating pregnant rats and neonatal rats with an anesthetic xenon gas mixture.

Claim 11 of the present application is directed to providing analgesia to a newborn subject in need of analgesia and claim 12 is directed to providing analgesia to a fetal subject in

need of analgesia. There is absolutely no description of providing analgesia to a newborn or fetal subject in Fukura. Rather, Fukara is directed, in its entirety, to investigating whether xenon affects neural network formation during perinatal development. Therefore, the only reason that xenon is administered to pregnant rats and neonatal rats is to study the sectioned forebrains of the neonatal and fetal rats to determine the effect of xenon on neuronal development in comparison to nitric oxide inhalation.

Fukara concludes that xenon is a safe anesthetic for perinatal neuronal development. (See Fukara at page 1357). There is no reason to believe, based on Fukara, that just because xenon is a safe anesthetic for the perinatal period of development, that it can or should be used as an analgesic in a newborn or fetal subject. In fact, there is a clear distinction between anesthesia and analgesia. Indeed, many anesthetics provide no analgesia at all, including common intravenous anesthetics such as propofol, etomidate, and thiopental. Further, as stated above, nitrous oxide, an anesthetic that shares common properties with xenon and which is reported to provide analgesia to adults, was found ineffective in providing analgesia to neonatal rats. For at least these reasons, Applicants submit that claims 11 and 12 (and all claims that depend therefrom) are not anticipated by Fukara and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 102 by Lane

Claims 12 and 17 stand rejected as being allegedly anticipated by Lane et al. (Science 190, 210(4472), 899-901) ("Lane"). Applicants traverse this rejection. Lane is concerned with determining whether administering xenon as an anesthetic to pregnant rats yields teratogenic effects. There is absolutely no mention of administering xenon to a mother of a fetal subject where the fetal subject is in need of analgesia, as recited by claim 12. Further, there is no reason to believe, based on Lane, that just because xenon is used as an anesthetic in a pregnant rat that it can even achieve analgesia for the pregnant rat's fetus or that it should be used to provide analgesia for the fetus. As mentioned above, there is a clear distinction between anesthesia and analgesia. If Lane suggests anything, it is using xenon as an anesthetic since xenon was found not to have tetrogenic effect and since Lane concludes with the inquiry of whether xenon should replace nitrous oxide for clinical anesthesia. (See Lane page 901). Again, there is no suggestion at all of using xenon as an analgesic in any rat, let alone a pregnant rat to provide analgesia to the

fetus. For at least these reasons, Applicants submit that claim 12 (and all claims that depend therefrom) are not anticipated by Lane and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 103 by Fukara in view of Georgieff and Fishman

Claims 11-20 stand rejected as being allegedly rendered obvious by Fukara in view of U.S. Patent No. 6,197,323 to Georgieff ("Georgieff") and U.S. Patent No. 5,099,834 to Fishman ("Fishman") and further in view of Ohashi. Applicants traverse this rejection. As mentioned above, Ohashi is not prior art and Fukara does not describe administering xenon to a newborn or fetal subject in need of analgesia. Further, neither Georgieff nor Fishman describe this subject matter. Georgieff is directed to a liquid xenon emulsion that can be used as an anesthetic (See Abstract). Although Georgieff mentions that xenon has an analgesic action, there is no indication of using xenon as an analgesic in a fetal or newborn subject. In fact, just because xenon may be used as an analgesic in an adult patient does not mean that it can be used as an analgesic in a fetal or newborn subject. For instance, as described in the present specification:

> the expectation that efficacious analgesic drugs in adults will exert the same beneficial effects in neonates has been challenged by our recent report that nitrous oxide (N_2O) is ineffective in neonatal rats because the immature pain pathways cannot activate the descending inhibitory pathway in response to nociceptive stimuli. . . Experiments have shown that N_2O lacks antinociceptive effects against thermal.. . and inflammatory. . . stimulation in rats under 3 weeks of age. If extrapolatable to humans, this would mean that N_2O is ineffective as an analgesic agent in subjects up to and including the toddler stage. A similar rationale was thought to apply to the use of xenon as an analgesic agent.

Page 1, line 22 to page 2, line 2. Therefore, it cannot be assumed that just because an agent has an analgesic effect in adults it will necessarily have an analgesic effect in a fetal or newborn subject.

With respect to Fishman, this reference does not cure the deficiencies of Georgieff as this reference does not describe using xenon to provide analgesia to a newborn or fetal subject. Rather, Fishman mentions using xenon as an anesthetic throughout (See e.g., Abstract; col. 2, lines 54-55; col. 4, lines 28-30; and col. 5, lines 37-43). Again, as stated above, there is a clear distinction between anesthesia and analgesia. Fishman at most, only alleges (without presenting any data) that xenon is non-toxic in fetuses. (See col. 4, line 11). There is still no reason to believe that xenon can or should be used to provide analgesia to a fetus. Avoiding toxicity is

obviously desirable, but this does not provide a reason for one skilled in the art to use xenon as an analgesic in a fetal or newborn subject. For at least these reasons, Applicants submit that claims 11 and 12 (and all claims that depend therefrom) are not rendered obvious by the combination of Fukara, Georgieff, Fishman and Ohashi and Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON LLP

Dated: September 14, 2007 By: /

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